

May [ ], 2019

The Honorable Alex M. Azar II  
Secretary, U.S. Department of Health &  
Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

The Honorable Seema Verma  
Administrator, Centers for Medicare and  
Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

Dear Secretary Azar and Administrator Verma,

We are writing today to express our deep concern with the Centers for Medicare and Medicaid Services' (CMS') plan to include non-invasive ventilators in the Medicare Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) competitive acquisition program. We are concerned that this action will result in access problems for Medicare beneficiaries who depend on home ventilators to breathe and urge you to reconsider your plans.

Under your leadership, Medicare has taken strides to improve access to and the quality of durable medical equipment (DME) in the home. Specifically, CMS has issued new regulations to overhaul Medicare's competitive bidding program and to enhance the adequacy of Medicare payments in rural areas not subject to bidding. CMS issued a press release in March outlining its plans for implementing the next round of bidding this summer and unveiled plans to include non-invasive ventilators in the next round.

Invasive and non-invasive ventilators are highly specialized and care-intensive devices that allow fragile, medically complex patients to remain in their home while facing the challenges posed by devastating neuromuscular diseases like ALS and terminal respiratory conditions like end-stage COPD. In addition to mechanically facilitating patients' breathing, ventilators are accompanied by varying degrees of respiratory therapy, device training, remote and in-home monitoring, as well as requiring emergency repair and maintenance. All of this support and all essential accessories such as tubing, masks, and filters, as well as the device itself, are currently subject to one flat monthly payment from Medicare as part of the "frequent and substantial servicing" category.

Even brief delays in access to clinical ventilator support can prove dangerous or even fatal and would likely mean that many patients are no longer able to receive their care at home. Increased emergency room visits, hospitalizations, and institutionalizations could quickly offset any savings from bidding this item—and would certainly reduce quality of life for Medicare beneficiaries. As you know, Medicare rates have implications for other populations, including children on Medicaid and CHIP, active duty military and their families on TRICARE, and veterans served by the VA, among others. The adequacy of Medicare payment for critical services like home ventilatory care is paramount.

Congress has never specifically directed the Secretary to competitively bid ventilators, and Medicare has never attempted to bid any items within its entire DME category of devices requiring frequent and substantial servicing. CMS has never proposed including ventilators in the

program through rulemaking and we would encourage you to solicit such input on the record before doing so. CMS recently announced plans to include noninvasive ventilators in Medicare's competitive bidding program in a press release. We urge you to reconsider these plans.

Sincerely,